SUPPORT FOR THE AMENDMENT

The amendment to Claim 1 is supported by the test disclosed at pages 22-25 of the present specification. Further, all appropriate claims have been amended to remove multiple dependency. No new matter is believed to be introduced by the above amendment.

REMARKS

Claims 1-16 and 18-20 are pending. Favorable reconsideration is respectfully requested.

At the outset, Applicants would like to thank Examiner Pulliam for helpful suggestions during the courteous discussion held on January 15, 2003, in overcoming the rejections in the outstanding Office Action. Further, Applicants thank Examiner Pulliam for indicating that the above amendment would further favorable prosecution.

The rejection of Claims 1-20 under 35 U.S.C. §102(b) and/or §103(a) over Yajima et al is believed to be obviated by the above amendment. It should be noted that the rejection is based on the English-language translation of the Abstract of Yajima et al and not the full English-language translation. Although the Office treats the Abstract and the full disclosure as separate entities, Applicants are entitled to request the Examiner to provide Applicants with a full English-language translation of a reference that the Examiner cites the Abstract thereof (see pages 1683 to 1684 of the attached copy of Ex parte Gavin, 62 USPQ2d 1680 (2001)). Under Gavin, Applicants are respectfully requesting the full English-language translation of Yajima et al. Further, if a further Office Action is issued, Applicants respectfully request it to be a non-final Office Action for it is clear that the Abstract of Yajima et al cannot possibly be enabled since it is a separate entity from the disclosure therefrom and does not provide any motivation and/or guidance to obtain the claimed

invention. Accordingly, Applicants' amendment to Claim 1 cannot possibly be construed to spark further search and/or new grounds of rejection based upon a non-enabled reference such as the Abstract of Yajima et al.

Yajima et al discloses, at best, a composition for oral preparation, containing a complex formed by an unpleasantly tasting drug and a polymer with a substance having a low-melting point, as well as a sugar alcohol (see Abstract).

In direct contrast to Yajima et al, the claimed invention relates to a pharmaceutical composition comprising a drug having a disagreeable taste, a wax, and a sugar alcohol. Further, the composition has a particle size ranging from 50 to 200 μm and is able to flow through a tube having a diameter of at most 1 mm without clogging the tube. The example at page 22-25 of the present specification demonstrate that such a composition clearly has no clogging problems.

In light of the above, it is clear that the English-language translation of the Abstract is not enabled. In *arguendo*, the cited reference fails to provide motivation to optimize the composition disclosed therein to have a particle size of from 50 to 200 μm and have the ability to flow through a tube having a diameter of at most 1 mm without clogging. Therefore, one reading the cited references, at best, is left with merely picking and choosing from a multitude of characteristics of the disclosed composition without any disclosure, guidance and/or enablement of such characteristics. Therefore, Yajima et al fails to disclose the claimed composition. Further, no *prima facie* case of obviousness can be sustained based upon the English-language Abstract of Yajima et al. Due to its lack of enablement, as well as it failure to disclose and/or suggest of all claim limitations, Yajima et al can not possibly anticipate the claimed invention. Further, is fails to disclose or suggest all claim limitations,

Yajima et al can not possibly sustain a *prima facia* case of obviousness. Accordingly, withdrawal of these grounds of rejection are respectfully requested.

Applicants respectfully submit that the present application is now in condition for allowance. Favorable reconsideration is respectfully requested. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact the undersigned by telephone.

Respectfully submitted,

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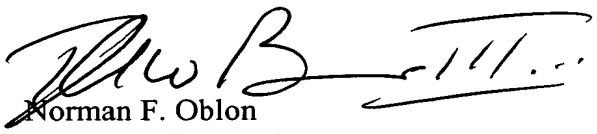
MAIER & NEUSTADT, P.C.



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Serial No: 09/926,123
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IN THE CLAIMS

--1. (Amended) A granular pharmaceutical composition comprising a drug having a disagreeable taste, a wax, and a sugar alcohol, wherein the composition has a particle size ranging from 50 to 200 μm and is able to flow through a tube having a diameter of at most 1 mm without clogging the tube.

3. (Amended) A granular pharmaceutical composition according to claim 1 [or 2], wherein the drug having a disagreeable taste is slightly soluble in the wax.

4. (Amended) A granular pharmaceutical composition according to claim 1 [or 2], wherein the drug having a disagreeable taste is soluble in water and slightly soluble in the wax.

5. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 4] claim 1, wherein the wax has a melting point of 40-150°C.

6. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 5] claim 1, wherein the wax is a member selected from the group consisting of hydrogenated oils, fats and oils of vegetable or animal origin, higher alcohols, polyethylene

glycols, higher fatty acids, glycerin fatty acid esters, sucrose fatty acid esters, and combinations of two or more of these.

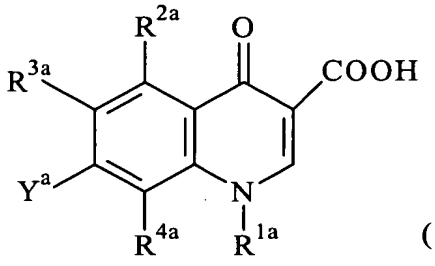
7. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 6] claim 1, wherein the sugar alcohol is a member selected from the group consisting of erythritol, xylitol, sorbitol, maltitol, and combinations of two or more of these.

8. (Amended) A pharmaceutical composition according to [any one of claims 1 through 7] claim 1, wherein the sugar alcohol has a heat of dissolution of not higher than -30 cal/g.

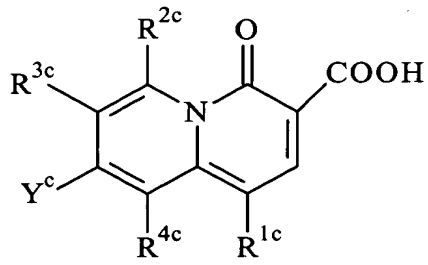
9. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 8] claim 1, wherein the sugar alcohol is erythritol and/or xylitol.

10. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 9] claim 1, wherein the drug having a disagreeable taste is a drug selected from the group consisting of cetraxate hydrochloride, ecapapide, nefiracetam, talampicillin hydrochloride, indenolol hydrochloride, hydralazine hydrochloride, chlorpromazine hydrochloride, tiaramide hydrochloride, berberine chloride, digitoxin, sulpyrine, azelastine hydrochloride, etilefrine hydrochloride, diltiazem hydrochloride, propranolol hydrochloride, chloramphenical, aminophyllin, erythromycin, clarithromycin, phenobarbital, calcium pantothenate, indeloxazine hydrochloride, aminoguanidine hydrochloride, bifemelane hydrochloride, 7β-[2-(2-aminothiazol-4-yl)-2-(Z)-hydroxyiminoacetamido]-3-N,N-dimethylcarbamoyloxymethyl-3-cephem-carboxylic acid 1-(isopropoxycarbonyloxy)ethyl

ester hydrochloride, (E)-3-(2-methoxy-3,6-dimethyl-1,4-benzoquinone-5-yl)-2-[5-(3-pyridyl)pentyl]-2-propenic acid, aminophylline, theophylline, diphenhydramine, metaclopramide, phenylbutazone, phenobarbital, ampicillin, cimetidine, famotidine, nizatidine, acetaminophen, epirizole, pyrazinamide, caffeine, ethionamide, carvedilol, ranitidine hydrochloride, roxatidine acetate hydrochloride, imipramine hydrochloride, ephedrine hydrochloride, diphenhydramine hydrochloride, tetracycline hydrochloride, doxycycline hydrochloride, naphazoline hydrochloride, noscapine hydrochloride, papaverine hydrochloride, dextrhomethorphan hydrobromide, timepidium bromide, chlorphenilammonium maleate, alimemazine tartrate, pilsicainide hydrochloride, N-methylscopolamine methylsulfate, cinepazide maleate, arginine hydrochloride, histidine hydrochloride, lysine hydrochloride, lysine acetate, clopidogrel sulfate; crude drugs or extracts thereof; pyrridonecarboxylic acid compounds represented by formulas (1) through (4) and salts thereof:



(1)



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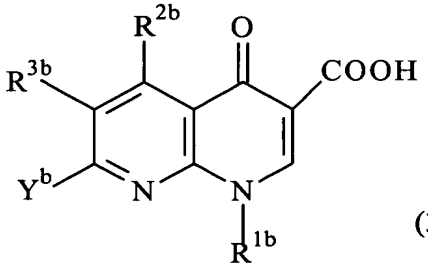

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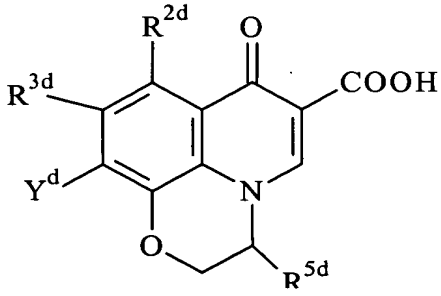

(4)

[(]wherein each of R^{1a}, R^{1b}, and R^{1c} represent a C1-C6 linear or branched alkyl group which may have a substituent, a C3-C6 cyclic alkyl group which may have a substituent, an aryl group which may have a substituent, or a heteroaryl group which may have a substituent;

each of R^{2a}, R^{2b}, R^{2c}, and R^{2d} represents a hydrogen atom or a C1-C6 linear or branched alkyl group which may have a substituent; or an amino group each of R^{3a}, R^{3b}, R^{3c}, and R^{3d} represents a hydrogen atom or a halogen atom; R^{4a} or R^{4c} represents a hydrogen atom, a halogen atom, a C1-C6 linear or branched alkyl group which may have substituent; or a C1-C6 linear or branched alkoxyl group which may have a substituent;

R^{5d} represents a hydrogen atom or a C1-C6 linear or branched alkyl group which may have a substituent; and

each of Y^a, Y^b, Y^c, and Y^d represents a nitrogen-containing group[)].

11. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 9] claim 1, wherein the drug having a disagreeable taste is ofloxacin.

12. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 9] claim 1, wherein the drug having a disagreeable taste is levofloxacin.

13. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 9] claim 1, wherein the drug having a disagreeable taste is clopidogrel sulfate.

14. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 13] claim 1, wherein the drug having a disagreeable taste and the wax are mixed at a ratio of 1:1 - 1:5 by weight, and the composition has a sugar alcohol content of at least 10% by weight.

15. (Amended) A granular pharmaceutical composition according to [any one of claims 1 through 14] claim 1, which is produced by melting the wax with heat; dispersing or dissolving therein the drug having a disagreeable taste; subjecting the resultant mixture to primary granulation to thereby obtain a granulated product; and mixing the granulated product with the sugar alcohol, or subjecting the granulated product and the sugar alcohol to secondary granulation.

17. (Canceled).

19. (Amended) A pharmaceutical product for oral administration comprising [a] the granular pharmaceutical composition [as recited in any one of claims 1 through 17] claim 1.--